IsoRay MEDICAL

K111931

AUG - 5 2011

3.0 Section C: 510(k) Summary Required by 21 CFR § 807.92

3.1 **Submitter**: IsoRay Medical, Inc.

3.2 **Address**: 350 Hills Street, Suite 106
Richland, WA 99354-5411

3.3 **Telephone and Fax Numbers**: 509-375-1202
(Fax) 509-375-3473

3.4 **Contact Person**: Fredric Swindler
fswindler@isoray.com

3.5 **Date of preparation of this Summary**: 07/08/2011

3.6 **Device Name, Regulatory and Classification Information**:

3.6.1 **Trade Name**: GliaSite® RTS

3.6.2 **Common Name**:

3.7 **Classification Name**: Radionuclide Brachytherapy Source (Per 21CFR §892.5730)

3.8 **Marketed device to which equivalence is claimed**: The modified GliaSite RTS that is the subject of this submission is substantially equivalent to the GliaSite RTS as described in 510(k) #K003206 (SE 04/25/2001).

3.9 **Product Description**: The GliaSite® RTS is a radiation therapy system that includes the GliaSite Catheter Tray, Iotrex™ Radiotherapy Solution, and the GliaSite RTS Access Tray. The GliaSite Catheter Tray includes the GliaSite catheter and accessories to assist with the implantation of the catheter. The GliaSite catheter is a double balloon applicator that positions the radiation source within the resected cavity for radiation delivery. The GliaSite RTS is provided in three balloon sizes: 2 cm, 3 cm, and 4 cm.

Iotrex is an ^{125}I radiotherapy solution and is the radiation source to be used with the GliaSite RTS. The GliaSite RTS Access Tray contains the items needed for the afterloading and retrieval of the Iotrex Radiotherapy Solution.

3.10 **Statement of intended use compared to the currently marketed predicate device**: The intended use of modified device is as follows:

> The GliaSite RTS is intended to deliver intracavity radiation therapy (brachytherapy) in patients with malignant brain tumors following resection surgery.

This is identical to the legally marketed predicate device, the GliaSite RTS as described in 510(k) No. K0003206 (SE 04/25/2001).

3.11 **Statement of Technological Characteristics**: The intended use and technological characteristics of the modified GliaSite RTS are identical to the GliaSite RTS predicate as described in 510(k) No. 003206. The comparison of the modified device to the legally marketed predicate device included implant duration, target sites, component materials and dimensions, radionuclide source and its characteristics, and clinical usage. Both proposed and predicate devices provide a means of delivering a radioisotope to a tumor or tumor cavity. Both proposed and predicate devices have identical dosimetric properties and utilize the Iotrex Radiotherapy Solution with its ^{125}I(HBS) radiation source.

3.12 **Safety and Effectiveness**: To ensure that the devices are safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to leak testing, testing for external contamination, apparent activity, sterility, pyrogens, and labeling. The required testing is defined by written and approved procedures that conform to the product design specifications. The testing for the GliaSite RTS is detailed in the Device Master Record.

350 Hills St., Suite 106 - Richland, WA 99354-5411
Phone: 509.375.1202 Toll Free: 877.447.6729 Fax 509.375.3473 info@isoray.com

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG - 5

Mr. Fredric G. Swindler
Vice President. Regulatory Affairs and Quality Assurance
IsoRay Medical
350 Hills St., Suite 106
RICHLAND WA 99354-5411

Re: K111931
Trade/Device Name: GliaSite Radiation Therapy System (RTS)
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: July 8, 2011
Received: July 8, 2011

Dear Mr. Swindler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

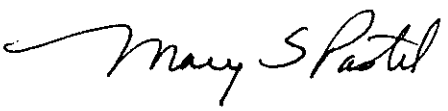
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

2.0 Section B

Indications for Use

510(k) Number: K111931

Device Name: GliaSite Radiation Therapy System (RTS)

Indications for Use:

The GliaSite RTS is intended to deliver intracavity radiation therapy (brachytherapy) in patients with malignant brain tumors following tumor resection surgery.

Prescription Use __X__ (Per 21 CFR § 801.109) OR Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111931